

ufactured For Lu Mar Laboratories, Springdale Arkansas"; (bag) "1 lb." (hand written); (can) "Lu Mar One Pound Sulfathiazole Sodium \* \* \* Manufactured for Lu Mar Laboratories Springdale, Arkansas."

RESULTS OF INVESTIGATION: All lots of the articles were repacked and labeled by the dealer.

LIBELED: 10-9-61, W. Dist. Ark.

CHARGE: 502(a)—while held for sale, the labeling, namely, the repack labels, contained false and misleading representations that the article (*piperazine wormer*) was adequate and effective for the removal of large roundworms (*Ascaridia*) from chickens and turkeys; and of large roundworms (*Ascaris*) and nodular worms (*Oesophagostomum*) from hogs; (*sulfathiazole sodium*) was adequate and effective for the treatment of all staphylococcal infections in cattle, swine, horses, mules, sheep, goats, and poultry; 502(b) (1)—the articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e) (1)—(*sulfathiazole sodium*) the label failed to bear the common or usual name of the drug; and 502(f) (1)—(*piperazine wormer* and *sulfathiazole sodium*) the labeling failed to bear adequate directions for use.

DISPOSITION: On 11-17-61, Luther Martin, claimant, filed an answer denying that the articles were misbranded. On 1-4-62, the claimant having consented, the court entered a decree of condemnation and the articles were relabeled.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

6875. Imitation Hydrodiuril tablets. (F.D.C. No. 46455. S. No. 69-581 R.)

QUANTITY: 1 bottle of 550 tablets at Chicago, Ill., in possession of Lazar Drugs, Inc.

SHIPPED: Prior to 2-28-61, from outside the State of Illinois.

LIBELED: 9-18-61, N. Dist. Ill.

CHARGE: 501(d) (2)—while held for sale, a substance other than *Hydrodiuril tablets* was substituted for *Hydrodiuril tablets*; 502(i) (2) and (3)—the article was an imitation of another drug, and was offered for sale under the name of another drug; and 502(a)—the label designation "MSD Tablets Hydrodiuril \* \* \* 50 mg. Merck Sharp & Dohme" was false and misleading as applied to an article which was not 50 mg. tablets of *Hydrodiuril* manufactured by Merck Sharp & Dohme.

DISPOSITION: 10-19-61. Default—destruction.

6876. Insta-Pep tablets. (F.D.C. No. 46765. S. No. 13-789 T.)

QUANTITY: 13 cases, 6 combination pkgs. each, 1 50-tablet btl. and 1 25-tablet btl. in each pkg., at Gary, Ind.

SHIPPED: 3-8-61, from New York, N.Y., by Drug Research Corp.

LABEL IN PART: (Btl. and ctn.) "Insta-Pep with Dynamol and 'Vitamin Feed' For prolonged Vitamin-Mineral Release A high potency therapeutic *Vitamin-Iron Formula* Sole Distributors: Drug Research Corp., New York, N.Y. Each Tablet Contains: \* \* \* Cobalamin Concentrate (Vit. B<sub>12</sub> Activity) 3.0 mcg. Dynamol (D.R.C. Brand of Caffeine Alkaloid Anhydrous) 3.0 gr. \* \* \*

\*See also Nos. 6864, 6866.

A Stimulant and therapeutic formula"; (comb. pkg.) "Insta-Pep A Fast-Acting Stimulant Combined With High Potency Vitamin-Iron Formula Each Tablet Releases Vitamins-Minerals Three Times a Day."

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained about 50 percent of the declared amount of vitamin B<sub>12</sub>.

**LIBELED:** 12-5-61, N. Dist. Ind.

**CHARGE:** 501(c)—while held for sale, the strength of the article differed from that which it was purported to possess, since the article contained less than the declared amount of vitamin B<sub>12</sub>; 502(a)—the label statement "Cobalamin Concentrate (Vit. B<sub>12</sub> Activity) 3.0 mcg." was false and misleading; 502(a)—when shipped, the name of the article "*Insta-Pep*" and certain statements on its label contained false and misleading representations and suggestions that the article was adequate and effective to provide instant pep, that the article was a high potency therapeutic vitamin and iron formula, and that "Dynamol" was an important active ingredient.

**DISPOSITION:** 1-18-62. Default—destruction.

**6877. Ferrous sulfate tablets.** (F.D.C. No. 46323. S. No. 97-303 R.)

**QUANTITY:** 1 drum containing 42,000 tablets at Buffalo, N.Y.

**SHIPPED:** 3-13-61, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

**LABEL IN PART:** (drum) "Tablets Ferrous Sulfate USP 0.324 gm (5 gr.) Stock No. 1-193-300 Lot No. 8190 Cowley Pharmaceuticals, Inc., Auburn, Mass. \* \* \* Adult dose: 1 or 2 tablets 3 times daily \* \* \* For Iron Deficiency Anemia."

**RESULTS OF INVESTIGATION:** Analysis showed that the article contained ferrous sulfate in excess of amount permitted.

**LIBELED:** 8-29-61, W. Dist. N.Y.

**CHARGE:** 501(b)—when shipped, the strength of the article differed from the USP Standard for *Ferrous Sulfate Tablets*; 502(a)—the label statement "Ferrous Sulfate USP" was false and misleading as applied to the product which failed to conform to the USP Standard for *Ferrous Sulfate Tablets*.

**DISPOSITION:** 1-19-62. Default—destruction.

**6878. Decavitamin tablets.** (F.D.C. No. 46105. S. No. 7-427 R.)

**QUANTITY:** 41 cases, each containing 144 100-tablet btls., and 11 100-tablet btls., at Worcester, Mass.

**SHIPPED:** During May 1958, from Lathrop, Calif. This was a return shipment.

**LABEL IN PART:** "Decavitamin Tablets, USP \* \* \* Each tablet contains: \* \* \* Cyanocobalamin (Vit. B-12) 2 mcg."

**RESULTS OF INVESTIGATION:** Examination showed that the article contained approximately 75 percent of the declared amount of vitamin B<sub>12</sub>.

**LIBELED:** 7-24-61, Dist. Mass.

**CHARGE:** 501(c)—while held for sale, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "Cyanocobalamin (Vit. B-12) 2 mcg." was false and misleading as applied to an article which contained less than the declared amount of vitamin B<sub>12</sub>.

**DISPOSITION:** 11-6-61. Default—destruction.